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778,813 AMENDED SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale Sheet 1*

Fig. 1.

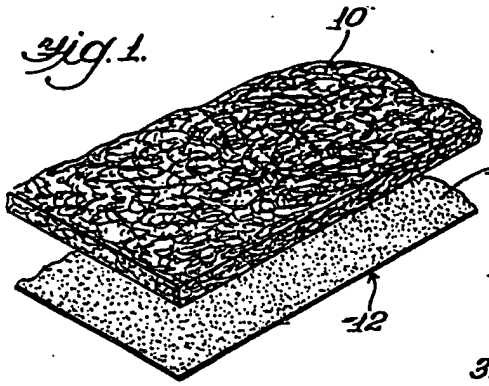
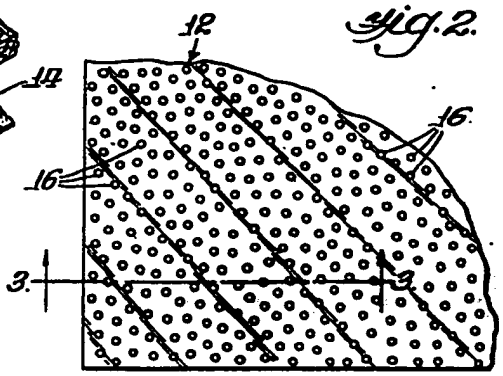


Fig. 2.



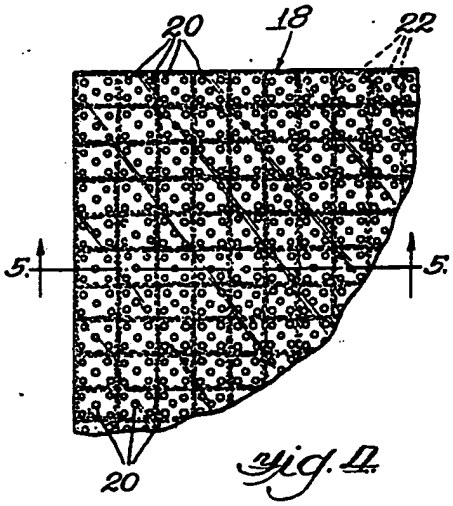


Fig. 4.

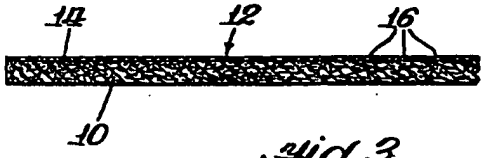


Fig. 3.

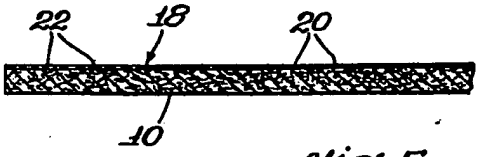


Fig. 5.

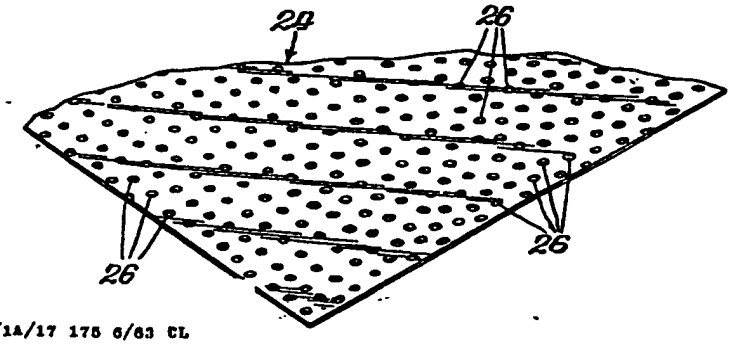


Fig. 6.

DS 75312/1A/17 175 6/63 CL

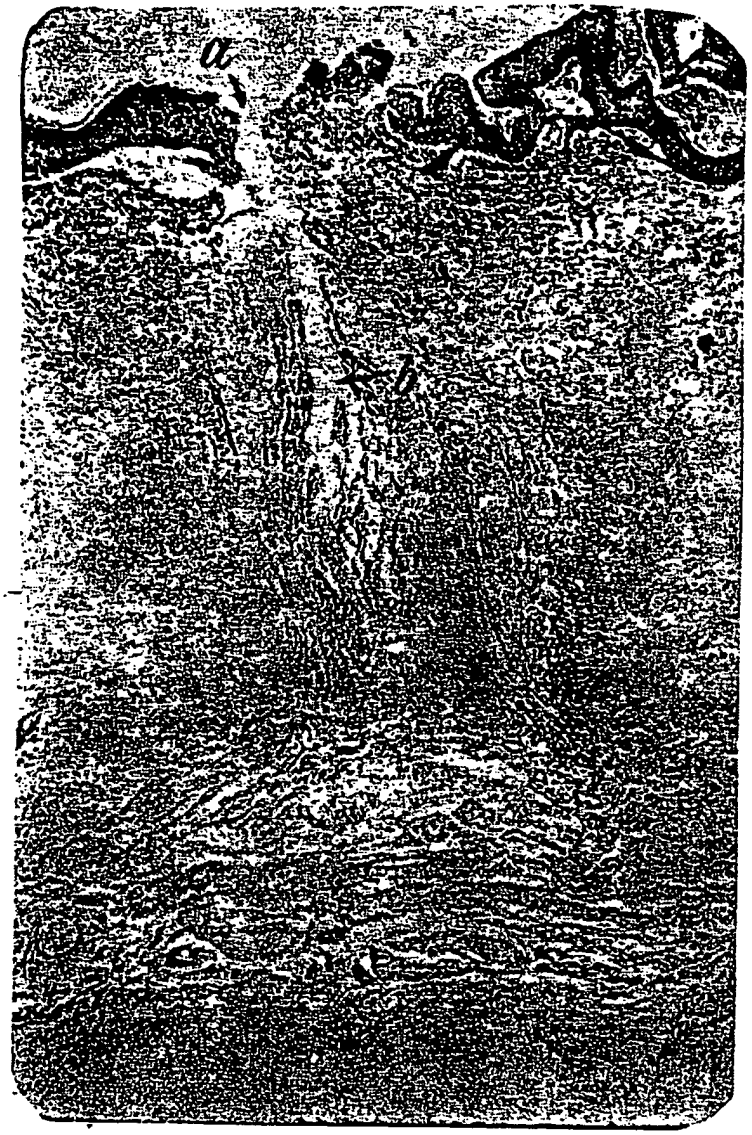


fig. 7.

75312/1/17 175 6/63 CL

778,813 AMENDED SPECIFICATION

3 SHEETS

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SHEETS 2 and 3

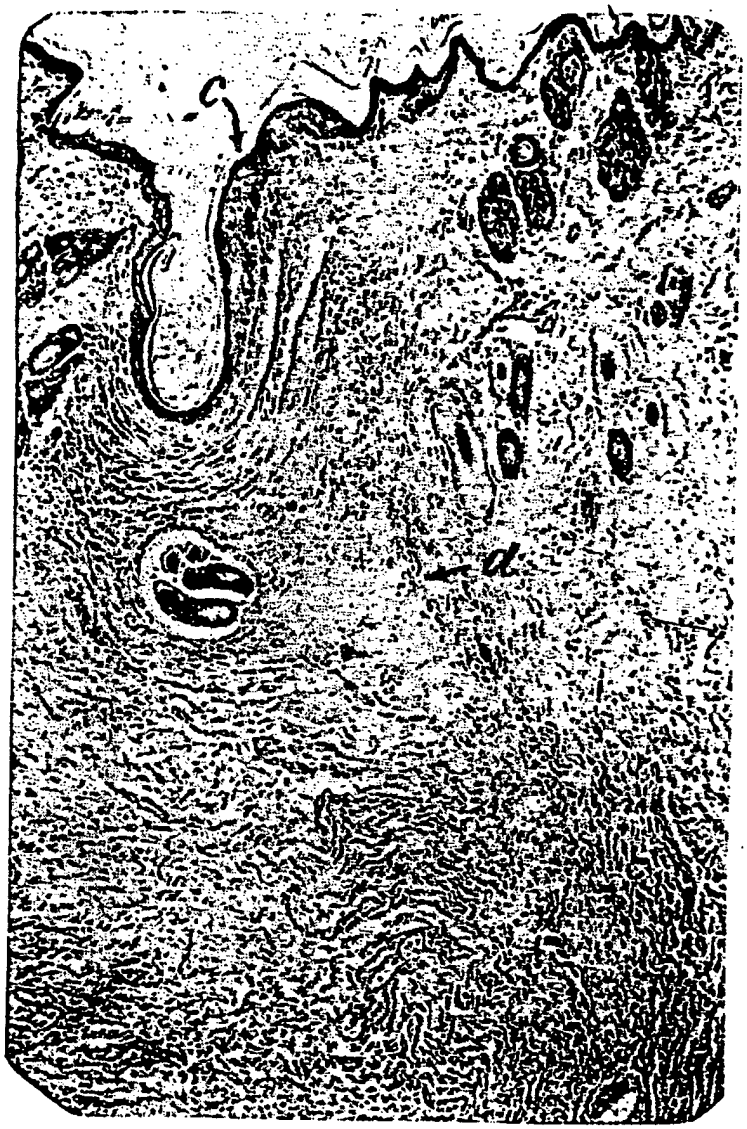

Fig. 8.

AMENDED SPECIFICATION

Reprinted as amended in accordance with the Decisi n of the Superintending Examiner acting for the Comptroller dated the Second day of May, 1963, under Section 14, of the Patents Act, 1949.

PATENT SPECIFICATION

DRAWINGS ATTACHED

778,813

778,813

Date of filing Complete Specification: Nov. 29, 1955.

Application Date: Dec. 1, 1954. *No. 34815/54.*

Complete Specification Published: July 10, 1957.

Index at acceptance:—Class 81(2), E1H.

International Classification:—A61l.

COMPLETE SPECIFICATION

Improvements in Surgical Dressings

We, THE KENDALL COMPANY, a Corporation organized and existing under the laws of the State of Massachusetts, at Boston, State of Massachusetts, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention is concerned with sterilizable surgical dressings for an animal body, particularly with dressings whose normal function is the protection of wounds and the absorption of wound fluids.

The natural healing process in animals is a very complicated, little understood, process. But assuming the wound is not infected and not again injured, there is normally a healing potential which varies not only with the type of wound but with the species, the individual within the species, and in fact with the temporary state of health of the particular individual involved. Nevertheless, disposal of irreparable damaged tissue is almost invariably one of the initial phases of wound healing. The wound bleeds annd weeps, washing itself in the process. Eventually this wound exudate becomes thickened and solidifies into an eschar (by which is meant any scab, eschar or other crust formed upon the body) which, barring infection, normally remains in place until the wound is completely healed.

After the initial exudating stage has ceased and the eschar has formed, small delicate buds of granulating tissue begin to form—grow larger and consolidate under the scab, at the same time preparing a bed for the forming epithelial cells. The latter spread from the peripheral edges of the wound as the bed is made ready until they also merge to force off the now useless eschar.

Unfortunately, with natural healing processes, the wound too often becomes infected with the result that very serious complications such as toxemia, septicemia, pyemia or gangrene may occur and, in any event, healing may be very much delayed.

To avoid the probability of such complications, it has been accepted practice, after disinfecting such wounds as may be contaminated to cover wounds with absorbent and protective material such as surgical gauze prior to the formation of the eschar. While such dressings have definite advantages their use admittedly detracts from the natural healing potential of the particular wounds dressed.

Ideally surgical dressings should have many properties. They should, of course, be soft and pliable initially and during use so that they will both conform to the wound and provide maximum comfort to the patient. They should present a barrier to bacterial infection. They should pad the wound to protect it from further injury. They should be easily applied and easily removed. They should be sterile and non-toxic. They should not interfere with normal wound healing. They should absorb excess fluids exuded from the wound.

It is significant that, although the properties of ideal surgical dressings have been known for many years, no dressing as yet in use has had all or even most of the ideal properties. The two dressings in almost universal use today, gauze and petrolatum coated gauze, have very serious well recog-

[*Price 4s. 6d.*]

nized deficiencies, the most serious of which, perhaps, is the difficulty attending their removal.

Where fibrous material such as gauze is in immediate contact with the wound, the wound exudate, a complex and largely proteinaceous adhesive material, extends into the interstices and around the fibres of the dressing so that the latter is eventually adhesively and mechanically anchored into the scabby covering. When the dressing is changed, as it frequently must be with certain types of wound, the scabby protective covering is disrupted if not entirely removed. In other cases, particularly with certain types of wound, such as serious burns and skin graft sites, buds of new tissue may actually grow into and around the fibrous interstices. Removal of dressing so embedded and bound is not only a most painful procedure but one which causes destruction of the delicate regenerating tissues with resultant delayed healing and often unsightly scarring. In addition, such reopening of the wound invites possible infection.

Attempts have been made, of course, to eliminate the disadvantages of plain gauze dressings but the most widely used substitute for plain gauze, petrolatum coated gauze, is messy and even though a number of layers are used, the petrolatum tends to liquefy at body temperature and soak into the dry dressing above. At the same time, such dressings tend to introduce into the wound foreign material which reacts to delay wound healing. Petrolatum coated gauze in most cases is more easily and less painfully removed than plain gauze, but it nevertheless shows, in a high percentage of cases, the same troublesome wound sticking with attendant induced capillary bleeding. Further, because such dressings absorb and transfer wound fluids poorly, they produce a wet saturated condition not conductive to rapid healing.

It is the object of this invention to provide an improved unitary surgical dressing of unique character, and superior to any other surgical dressing on the market today.

The invention provides a sterilizable unitary, non-adherent dressing for an animal body which is substantially non-adherent to wounds and is non-toxic and flexible at body temperature and which comprises a water-insoluble backing layer of sheeted fibrous material of high capillarity and a smooth, conformable, lubricious, water-insoluble body-contacting film of synthetic plastic material, the film having numerous openings for the passage of body exudates through the film and into the backing layer and being united to the backing layer over substantial areas between the openings, by heat sealing or by means of a flexible water-insoluble cement, so as to be inseparable from the backing layer by water. The expression "sheeted fibrous material" as used herein does not include sponge but means material in the form of a sheet formed from inter-connected fibres, which affords at its film-contacting surface a sufficiently uniform coverage over the openings in the film and which is sufficiently coherent to prevent ready shedding of the fibres in use of the dressing.

We are aware that surgical dressings have been proposed, comprising an absorbent fibrous backing and a smooth, perforated body-contacting film, e.g. of regenerated cellulose, attached to the backing. So far as we are aware, however, such dressings have not been commercially available.

The composite dressing according to the invention having the desired property of permitting the formation of thin wound eschars from which the dressing may be removed without eschar disruption, has two essential elements, namely the fenestrated lubricous film and the absorbent backing layer. As already noted the two elements are united face to face by heat sealing or by an interposed adhesive so that bonds exist between the elements at points between the fenestrations in the film.

Certain specific embodiments of the invention will now be described in more detail, by way of example, with reference to the accompanying drawings; in which:—

Fig. 1 represents a fragmentary view of typical components of the dressing according to the invention before final assembly and fenestration.

Fig. 2 illustrates a typical dressing according to the invention.

Fig. 3 is a cross-section on the line 3—3 of Fig. 2.

Fig. 4 illustrates a modification of the dressing in which the bonding of the components is intermittent.

Fig. 5 is a cross-section on the line 5—5 of Fig. 4.

Fig. 6 represents a modification of the film fenestrations of the dressing according to the invention.

Fig. 7 is a photomicrograph of one of a pair of originally like wounds upon initial removal of a plain gauze dressing which had remained in position for 14 days.

Fig. 8 is a photomicrograph of the other of the pair of originally like wounds, upon initial removal of a dressing according to the invention, which had also remained in position for 14 days.

In Fig. 1 the film portion 12 of the dressing is shown in the imperforate condition with a bonding layer 14 covering its top surface and with an absorbent backing layer 10 superimposed.

In Fig. 2 the assembled dressing is shown after the fenestrations 16 have been made in the film. In the modification shown in Figs. 4 and 5, the bonding layer is not continuous but is intermittent as indicated by

22. The holes in the film 18 may be somewhat compartmented as at 20 but preferably they are uniformly distributed over the entire film area. In Fig. 6, the film 24 is shown with circular holes arranged in a regular pattern as contrasted to the irregular fenestrations shown in Fig. 2.

It is highly important that an intimate and permanent contact exists between the film and the absorbent backing to ensure that the finished dressing has the desired properties. Unification throughout the whole surface area of contact is highly desirable but the dressing will still perform its function in a satisfactory manner without such complete unification if substantial bonding exists at points between the fenestrations in the film.

Accordingly, if the film and the absorbent backing are not united over the whole of their contacting surfaces, they must be united over substantial areas between the openings, by which we mean over such areas as will maintain an intimate and permanent contact between the film and the absorbent backing with the effect that the functional performance of the dressing is the same as if there were unification over the whole surface area of contact.

The film must be smooth and lubricious and should also present a continuous surface without appreciable roughness or graininess. Roughly surfaced or discontinuous media are abrasive and tend to produce rough uneven eschars which are easily abraded. The film should be relatively thin, its thickness being of the order of .01 inch or less and preferably of the order of .00025 inch. Where the film is too thick or non-conformable, particularly with films having high liquid contact angles, the dressing tends to perform improperly or inefficiently.

The film, in addition to thinness, must possess a high degree of conformability. It is preferred to use as the film a material such that, when a strip of film, one inch long and two inches wide, is tested on the Gurley R.D. Stiffness Tester 4171 by bending across the two inch width with ½ inch of the length of the strip projecting from the jaws of the testing machine, not more than 12 grams-force is required to bend it. Obviously, if the film is too stiff it will be uncomfortable but, in addition, it will fail to conform to the body sufficiently to create thin eschars.

Another important factor is the ratio of dry to wet initial modulus of elasticity of the film, which should not substantially exceed 100 to 1, because otherwise the film is distorted by moisture after application to a wound to such an extent that it no longer presents a smooth lubricious surface.

One of the most desirable features of a surgical dressing is its ability to withstand normal hospital sterilization which is essentially a heat process. Films which are to be used in dressings undergoing such sterilization must be capable of withstanding exposure to saturated steam at 240°F. and 12 pounds pressure for 15 minutes without deterioration and without shrinking more than 6% in any direction. Films capable of such conventional hospital sterilization are greatly preferred for the dressings according to the invention.

The film must of course be non-toxic, that is it must contain no primary irritants nor active sensitizers nor delay wound healing either in itself or because of any leachable ingredient. In general, the film should be completely insoluble in wound exudate with the exception that under certain conditions it may be desirable to incorporate in the film certain leachable medicaments.

Preferably the film is a preformed single thickness, .00025 inch thick, of extruded polyethylene terephthalate which may be prepared by any known process such as that described in U.S. Patent No. 2,650,213. A commercially available film which may not be completely polyethylene terephthalate but is perfectly satisfactory may be obtained from E. I. du Pont de Nemours & Company, Wilmington 98, Delaware, under the Registered Trademark "Mylar". This film in the preferred caliper is sufficiently pliable without modification for the dressings according to the invention. In some cases, with films not of extreme thinness, it may be desirable to plasticize the film to obtain sufficient flexibility, softness and conformability.

Obviously where plasticizers are utilized they must be non-toxic. Practically all plasticizers used in commercially obtainable films are satisfactory in this respect. Where a cement is used for uniting the film to the absorbent backing, particularly when the cement contains substantial amounts of rubber, it is preferred to use a non-migratory plasticizer preferably of the polymeric type, such as the oil modified polyesters of sebacic acid and other polybasic acids or other modified or unmodified polymerized condensation products of a polyhydric alcohol and a polybasic acid.

In general, where the film is such that it may be melted sufficiently for heat-sealing at a temperature below the scorch point of the absorbent backing, it is preferred to unite the film and the absorbent backing by pressure heat-sealing methods. Where the films themselves are not capable of being heat-sealed under such conditions they may be coated with a heat seal coating which permit this method of unification of the dressing to be utilized. But it may be expedient to utilize a quick drying cement for uniting the film to the absorbent backing.

The cement chosen may or may not be pressure-sensitive but it must be water-resistant or water-insoluble, non-toxic and flexible when dry. It should be capable of

firmly bonding the film to the absorbent backing. Cements which are to be utilized for heat-sterilizable dressings must be capable of withstanding the sterilizing temperature without deterioration and must have such non-flow characteristics, both at room temperature and when heated, as not to reduce unduly the porosity of the film. Examples of satisfactory cements for certain specific films are indicated in Table I. Also indicated in this table are the heat-sealability and steam sterilizability of the listed films, a + sign indicating that the particular film has the particular property.

A special type of cement bonding may be preferred where the film utilized is solvent cast upon a moving surface to which the film is detachably adherent. At a point in the drying sequence, the film becomes quite firm with its surface still tacky. At this point the absorbent backing may be pressed against the tacky film to firmly unite the two. This same procedure may be used where a film having a melting point below the scorch point of the backing is hot melt spread or extruded upon a chilled surface with the absorbent backing applied at the proper time to the exposed molten surface of the film.

TABLE I

Film	Heat Sealability	Steam Sterilizability	Cement Formula
Cellophane		+	A or B
Cellophane (moisture proof)		+	A or B
Cellulose acetate	+	+	A or C
Ethyl cellulose	+		C
Cellulose acetate-butyrate	+	+	A
Polyvinyl chloride	+	+	D
Vinyl chloride-acetate copolymer plasticized with 20% dioctyl phthalate	+		D
Vinyl chloride-acrylonitrile copolymer	+		C
Vinyl chloride-vinylidine copolymer		+	A
Vinyl chloride-octylacrylate copolymer	+		C
Polyamide (alcohol soluble)		+	A
Polyvinyl butyral	+		B
Polyethylene	+		E
Vinyl acetate-crotonic acid plasticized with 20% dibutyl phthalate			C
Polyethylene terephthalate		+	A

Suitable cements as indicated in Table I are as f llows:

FORMULA A

	Parts by weight
Solution x — polyvinyl ether	13.4
toluene	76.2
Solution y — water	10.3
70% aqueous solution wetting agent (Aerosol OT)	0.09
methyl cellulose	0.001
Add solution x to Solution y with rapid stirring.	

FORMULA B

	Parts by weight
Milled pale crepe rubber	350
High molecular weight polyisobutylene	200
Glyceryl ester of hydrogenated rosin	350
Low molecular weight polyisobutylene	100
Rubber Antioxidant	3
Heptane	2500

FORMULA C

	Parts by weight
55% solids polyvinyl acetate emulsion	100
Dibutyl phthalate	30
Water	20

FORMULA D

	Parts by weight
Neoprene latex 601A	100
"Geon" polyblend latex 552 (a dispersion of a blend of polyvinyl chloride and butadiene-acrylonitrile copolymer)	100

"Geon" is a Registered Trade Mark.

FORMULA E

	Parts by weight
Milled Pale Crepe Rubber	76.5
Glyceryl ester of hydrogenated rosin	76.5
Zinc oxide	56.5
Titanium dioxide	14.5
Antioxidant	1.0
Heptane	540.0

Where a cement is utilized, it is preferred to spread it as thinly as possible, consistent with firm bonding. The optimum dried thickness is in the range of about .0002 to .0006 inch with the wet thickness varying inversely with solids content.

The absorbent backings for the dressings of this invention must have a capillarity sufficient to take up and retain a minimum weight of water equal to four times the weight of the backing as determined by the Absorbency Test for Purified Cotton set out on page 678 of the fourteenth revision of the Pharmacopœia of the United States. It is preferred to use sheeted non-woven fibrous absorbent material such as is described in U.S. Patent No. 2,277,049, No. 2,528,793 or No. 2,625,733, particularly the cotton felts described in the latter two patents, or absorbent cellulose sheeted wadding made from wood pulp such as is sold under the trademark "Cellucotton" by International Cellucotton Products Co. Such sheeted absorbent material is preferred because it affords a more uniform coverage over the fenestrations in the film and hence presents a fairly uniform absorbent capacity throughout the area of the dressing.

Other sheeted fibrous absorbent materials, such as woven and knitted fabrics, or gauze, may be utilized, but in general are less satisfactory than the above-mentioned highly absorbent backings. Where gauze is utilized, it should preferably be as fine as 32 x 28 for the film contacting layer. Gauze as coarse as 20 x 12 is unsatisfactory for the film contacting layer but may be used for other layers.

In the layer of absorbent backing in immediate contact with the fenestrations in the films of the dressings of this invention, capillarity is very important. It has been found that materials which when submitted to the above mentioned Pharmacopœia test require more than 30 seconds for complete submersion are not suitable for this film contacting layer. Fibrous absorbent cellulosic sheet backings, the density of which is less than .05 grams per cubic centimeter, are also generally unsuitable. It has been found that a 30 square centimetre piece of film pierced with holes to give a total open area of .25% and having individual openings of the order of .125 mm diameter will not in sixty seconds pass any appreciable water into a vented vessel when subjected to a head of 1" of water. Yet the same film, when backed with a typical cotton felt backing and constituting a dressing according to the invention, will pass through the film and the backing behind it approximately 125 grams of water under the same conditions.

References herein to the sheeted fibrous material constituting the backing being "of high capillarity" are accordingly to be understood as meaning that the backing, as a whole, will take up and retain a minimum weight of water equal to four times the weight of the backing as determined by the aforesaid Absorbency Test for Purified Cotton and that the material of the film-contacting layer at least requires not more than 30 seconds for complete submersion when subjected to said Absorbency Test.

The dressings according to the invention may be sterilized if desired by electronic sterilization (i.e. by exposure to a high voltage electron beam such as that produced by a Van de Graaf accelerator) or by the now well known gaseous methods such as treatment with gaseous formaldehyde or by using various alkylene oxides such as ethylene oxide, either alone or in dilution with certain fire-suppressive gases such as carbon dioxide. Any film which may be heat or heat and steam sterilized, may also be sterilized by such gaseous methods. In addition, such relatively low temperature gaseous sterilization methods permit the use of a great many films which either have too low melting points to withstand heat sterilization temperatures or which are deteriorated by such heats. Examples of films which may be satisfactorily used when gaseous sterilization is employed are all of those appearing in Table I.

In general, it is preferred to unite the film portion of the dressing in an imperforate condition to the absorbent backing and thereafter to make the openings in the film by one of several methods.

Perhaps the most practical method of making the otherwise finished dressing porous is to punch holes from the film side by means of rolls studded with piercing pins such as the pins on a cotton card. When a cushion roll is used on the absorbent backing side of the dressing, quite irregular holes, slits, minor tears and punctures are produced, but dressings so perforated are entirely satisfactory both from the functional and commercial appearance standpoint. It is preferred to punch holes with a plurality of different sized pins and it has been found that using two rolls having about 230 triangular pyramidal pins per square inch, each pin being about .030" high and having a triangular base with an altitude of about .025" and a base of about .014" and four rolls having about 56 triangular pyramidal pins per square inch, each pin being about .045" high and having a triangular base with an altitude of about .045" and a base of about .030", an excellent dressing may be produced.

Where the film material is thermoplastic and has a relatively low melting point, it is possible to impart the proper porosity to the otherwise finished dressing by means of localized heating whereby holes are melted such as by hot wires imbedded in non-conductive rolls to form a well distributed pattern of fenestrations in the film.

Proper porosity may also be imparted to the film after unification of the dressing by means of knife bearing rolls which slit the film intermittently or porosity may be obtained by means of high frequency electrical sparking.

Where the fenestration of the film is to be done prior to unification of the dressing it is quite feasible to perforate the film with a well defined pattern of perforations similar to but usually smaller than the perforations in postage stamps. One must be particularly careful, however, especially with very small perforations, to avoid filling the perforations with laminating cement if that method of unification is used.

Proper porosity in films may also be obtained by a great many other methods such as froth casting, casting with removable suspended particles, air-jet piercing and the like.

The interrelated size, number and distribution of film holes or slits are extremely important for the proper functioning of the dressings according to the invention. It is obvious that the holes must be of such size and number as to pass at least a minimum of wound exudate. In general, it has been found that film holes of about .2 mm diameter spaced approximately .75 mm apart are especially suitable. Generally speaking, an open area of less than .25% of the film area is inadequate for proper drainage whether distributed over the film area as numerous small holes or as relatively fewer larger holes. Holes smaller than .01 sq. mm. tend to be inadequate.

At the other extreme are films having fenestrations of such size that the dressings made from them can no longer be considered truly non-adherent. It has been found that where there are numerous holes in which a 5 mm circle may be inscribed, sticking of the absorbent backing to the wound through the holes, is very probable. But where there is a maximum of 10% or less of holes in which circles greater than 2 mm and up to 5 mm may be inscribed and the remainder of the holes are of such size that only circles having diameters less than 2 mm may be inscribed, the dressing will substantially retain its non-adherent character.

The films listed in Table I in calipers ranging from .00025 inch to .002 inch were spread with the cements indicated opposite them in wet thickness up to .0015 inch. While the spread coatings were still tacky, absorbent backings of cotton felt, flannel, 44/40 mesh gauze and wood cellulose sheet wadding all in thicknesses from about .002 to .25 inch were spread over the cement coat-

ings. After drying, the dressings were fenestrated by localized heating and by passing through card cloth covered rollers to give openings ranging non-uniformly from .0125 square mm to 12 square mm and open areas from .25 to 25%. Similar films indicated in Table I as heat-sealable were run with the same backings through heat seal rollers which produced both over-all surface sealing and fine mesh pattern heat sealing. These heat-sealed dressings were fenestrated in the same manner as the cement unified dressings. Similar films were first fenestrated and then heat-sealed to the absorbent backings. Samples of all of the dressings were sterilized by subjecting them to a mixture of 10% ethylene oxide and 90% carbon dioxide at a temperature of 80°F. for 6 hours. Additional samples indicated in Table I as being steam sterilizable were sterilized with saturated steam at 240°F. and 12 pounds pressure for 15 minutes. All of the dressings withstood sterilization without appreciable damage. All proved satisfactory as non-adherent dressings within their respective capacities as reflected by their respective thicknesses although those with the preferred cotton felt and wood cellulose sheet wadding appeared to be most desirable from a performance standpoint.

Proof of the effectiveness of the dressings of this invention is to be found first in the results of carefully controlled animal experiments and, secondly, in the findings of exhaustive clinical tests carried out on human surgical wounds.

The first animal experiments demonstrate dramatically the superiority, in the all-important quality of non-adherence, of the dressings of the invention compared to the two leading dressings in use today.

In these extensive experiments, similar paired like wounds placed symmetrically on opposite sides of each animal were dressed on one side with the dressings of the invention and on the other side with plain gauze and petrolatum coated gauze respectively. The dressings were removed after 7 days with comparative adherence as summarized in Table II.

TABLE II

Dressing	% of Wounds in which Adherence Occurred after 7 days
Gauze	93%
Petrolatum Coated Gauze	26%
Dressings of this Invention	0%

While none of the wounds dressed with the dressings of the invention showed adherence, sticking and disruption, these phenomena did occur in 93% of the wounds dressed with plain gauze and in 26% of the wounds dressed with petrolatum gauze.

The results of a second series of studies carried out on experimentally produced wounds demonstrates the superior and very surprising healing obtained in like wounds covered with the dressings of the invention.

Experimental wounds dressed with the dressings of the invention were microscopically compared, by a recognized authority on microscopic anatomy, with like wounds symmetrically placed on the same animals dressed respectively with gauze and petrolatum coated gauze. The dressings remained in position in each case for 14 days before removal. On fifteen rabbits tested, the dressings of the invention left wounds all of which showed advanced healing over those dressed with plain gauze. On another set f fifteen rabbits with like wounds dressed with petrolatum coated gauze and dressings of the invention, wounds dressed with the latter showed healing to be farther advanced in twelve of the fifteen pairs.

Referring now to the photomicrographs, in Fig. 7 delayed wound healing is evidenced by the complete lack of epidermal repair as indicated at point (a), by the lack of closure of the wound in the dermis extending from point (a) through point (b), and also by the cellular infiltration surrounding the wound track. By contrast, the advanced healing of the wound section in Fig. 8 is easily apparent even to the untrained eye. The epidermis is completely sealed (c) and only minor cellular infiltration marks the site of the healed wound extending generally from (c) to (d).

The results of clinical trial furnishes the final proof of the remarkable effectiveness of the dressings of the invention. Human wounds dressed with the dressings of the invention have good colour and present a clean appearance with a very thin slightly moist skin-like covering which quickly dries if the dressing is not replaced. Nearly a thousand

diverse cases of major and of minor surgery, the latter mostly severe traumatic wounds of the extremities, were dressed with the dressings of the invention and graded on lack of adherence, adequate absorption and non-interference with wound healing. All but eight of the performances in this clinical evaluation of the dressings of this invention were classified as excellent in all categories.

Although the invention is primarily useful in the treatment of wounds and burns, we have also found it useful in connection with the absorption of urine, menstruum and other liquid exudates of the body from whatever cause whether or not the discharge is such as to permit a hardened film to be formed upon the body.

The dressings according to the invention may therefore also be used as a sanitary napkin or diaper.

WHAT WE CLAIM IS:—

1. A sterilizable unitary, non-adherent dressing for an animal body which is substantially non-adherent to wounds and is non-toxic and flexible at body temperature and which comprises a backing layer of water-insoluble sheeted fibrous material of high capillarity and a smooth, conformable lubricious, water-insoluble body-contacting film of synthetic plastic material, the film having numerous openings for the passage of body exudates through the film and into the backing layer and being united to the backing layer over substantial areas between the openings, by heat sealing or by means of a flexible water-insoluble cement, so as to be inseparable from the backing layer by water.

2. A dressing according to claim 1, in which the film consists substantially of polyethylene terephthalate.

3. A dressing according to claim 1 or claim 2, in which the absorbent backing is cotton felt having a density greater than .05 grams per cubic centimetre.

4. A dressing according to claim 1 in which the film has a thickness not exceeding .01 inch, the maximum force required to bend a sample of the film 2 inches wide by one inch long on the Gurley R. D. Stiffness Tester 4171 being not more than 12 grams, the initial modulus of elasticity of the film when wet being not less than 1/100 the initial modulus of the film when dry, and the film having a multiplicity of discrete openings therethrough collectively constituting an open area not less than .25% of the area of the film.

5. A dressing according to claim 4, in which 10% or less of the film openings are of such size that a circle having a diameter no larger than 5 mm can be inscribed in any part of each of said openings, the remaining 90% or more of said openings being of such size that a circle having a diameter no larger than 2 mm can be inscribed in any part of each of said openings, the film being united to the absorbent backing at points between said openings.

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PROVISIONAL SPECIFICATION

Improvements in Surgical Dressings

We, THE KENDALL COMPANY, a Corporation organized and existing under the laws of the State of Massachusetts, at Boston, State of Massachusetts, United States of America, do hereby declare this invention to be described in the following statement:—

This invention is concerned with sterilizable surgical dressings, particularly with dressings whose normal function is the protection of wounds and the absorption of wound fluids.

The natural healing process in animals is a very complicated, little understood, process. But assuming the wound is not infected and not again injured, there is normally a healing potential which varies not only with the type of wound but with the species, the individual within the species, and in fact with the temporary state of health of the particular individual involved. Nevertheless, disposal of irreparable damaged tissue is almost invariably one of the initial phases f wound healing. The wound bleeds and weeps, washing itself in the process. Eventually this wound exudate becomes thickened and solidifies into an eschar (by which is meant any scab, eschar or other crust formed upon the body) which, barring infection, remains in place until the wound is completely healed.

After the initial exudating stage has ceased and the eschar has formed, small delicate buds of granulating tissue begin to form — grow larger and consolidate under the eschar. As they expand and fill in the contour they gradually push out the eschar, at the same time preparing a bed for the forming epithelial cells. The latter spread from the peripheral edges of the wound as the bed is made ready until they also merge to force off the now useless eschar.

Unfortunately, with natural healing processes, too often the wound becomes infected with the result that very serious complications such as toxemia, septicemia, pyemia or gangrene may occur and, in any event, healing may be very much delayed.

It is the object of this invention to provide an ideal unitary surgical dressing having a unique functionality and superior to any other surgical dressing on the market today.

We believe, that the theory of dressing functionality as accepted prior to the introduction of the dressings of this invention has been partially erroneous and inadequate in that it has permitted the formation of thick eschars. Such thick dried eschars have caused conventional dressings to perform unsatisfactorily during their removal from wounds. They have found that smooth, lubricious surfaces are ideal contact surfaces for wounds when properly combined in their completely new type of surgical dressing with its wholly unique functionality.

The invention provides a unitary, non-adherent wound dressing comprising a smooth, comformable, water insoluble film water inseparably united to a water insoluble absorbent backing, said dressing being non-toxic and flexible at normal body temperature, said film having openings therethrough to permit body exudates to pass through said film into said absorbent backing. Preferably the film is substantially polythene terephthalate. Preferably also the absorbent backing is cotton felt having a density greater than 0.5 grams per cubic centimetre. The film and the adhesive backing may conveniently be united by a flexible water-insoluble cement.

Prior to the introduction of the dressings of this invention, no one had realized the advantages of a substantially skin-thick eschar nor had any dressing been constructed or proposed which would give such a skin-like eschar. Consequently, properly perforated selected films and absorbent material of proper capillarity have never been united in the manner which has been found according to the invention to be essential to produce consistently and dependably thin eschars such as the dressings of this invention produce and which have the desirable advantages hereinafter set forth.

We have discovered that real non-adherence of surgical dressings to wounds is a result of this wholly new concept of dressing functionality whereby the wound is kept essentially dry, the exudate being separated from the wouhd and absorbed as it forms. Wounds dressed with dressing having this functionality develop a very thin skin-like eschar which is generally slightly moist until after the dressing is removed. Removal of such dressings is accomplished without disruption of the eschar skin.

The composite dressing according to the invention, having the desired functionality of forming thin wound eschars from which the dressing may be removed without eschar disruption, has two essential elements, a specific particularly fenestrated lubricious film and a sheet-like absorbent material of particular capillarity. The two sheet elements are surface united either by heat sealing or by a selected adhesive so that bonds exist between the fenestrations in the film.

It is highly important that an intimate and essentially non-displaceable contact between the selected film and the proper absorbent backing exist if the desired functionality is to be obtained in the finished dressing. Unification throughout the surface area of contact is highly desirable but the dressing will still perform its function in a satisfactory manner without such complete unification if substantial bonding exists between the fenestrations in the film.

The film must be smooth and lubricious with neither high nor low spots and without appreciable roughness or graininess. Roughly surfaced films are abrasive and may produce rough uneven eschars which are easily abraded. The film should be relatively thin of the order of ten thousands of an inch thick or less and preferably of the order of .00025 inch. Where the film is too thick, particularly with films having high liquid contact angles, the dressing ceases to perform properly.

The film, in addition to thinness, must possess a high degree of conformability. Where a strip of film one inch (½ inch nominal) by two inches is tested on the Gurley R.D. Stiffness Tester 4171 by bending across the two inch width, only those films which require 12 grams or less of force to bend them have the necessary pliability and conformability for the dressings of this invention. Obviously, if the film is too stiff it will be uncomfortable but, in addition, it will fail to conform to the body sufficiently to create thin eschars.

Another limitation upon the film utilized is the ratio of dry to wet initial modulus of elasticity. Where this ratio approaches the order of 100 to 1, the film is distorted by moisture after application to such an extent that it no longer presents a smooth lubricious surface and hence is no longer suitable for the dressings of this invention.

One of the most desirable features of a surgical dressing is its ability to withstand normal hospital sterilization which is essentially a heat process. Films which are to be used in dressings undergoing such sterilization must be capable of withstanding exposure to saturated steam at 240°F. and 12 pounds pressure for 15 minutes without deterioration and without shrinking more than 6% in any direction. Films capable of hospital sterilization are preferred for the dressings of this invention.

The film should be non-toxic f course, that is it should contain no primary irritants nor active sensitizers nor delay wound healing either in itself or because of any leachable ingredient. In general, the film should

be completely insoluble in wound exudate with the exception that under certain conditions it may be desirable to incorporate in the film certain leachable medicaments.

The preferred film material for use in the dressings according to the invention is extruded .00025 inch thick polyethylene terephthalate which may be prepared by any of the known processes such as that described in U.S. Patent No. 2,650,213. A commercially available film which may not be completely polyethylene terephthalate but is perfectly satisfactory may be obtained from E. I. du Pont de Nemours & Company, Wilmington 98, Delaware, under the tradename "Mylar". This film in the preferred caliper is sufficiently pliable without modification for the dressings of this invention. In some cases, with films not of extreme thinness, it may be desirable to plasticize the film to obtain sufficient flexibility, softness and conformability.

Obviously, where plasticizers are utilized they should be non-toxic. Practically all plasticizers used in commercially obtainable films are satisfactory in this particular. Where a cement is to be used in uniting the film and the absorbent backing, particularly when the cement contains substantial amounts of rubber, it is preferred to use a non-migratory plasticizer such as a polymeric type.

In general, where the film is such that it may be melted sufficiently for heat sealing at a temperature below the scorch point of the absorbent backing, it is preferred to unite the film and the absorbent backing by pressure heat sealing methods. Where the films themselves are not capable of being heat sealed under such conditions they may be coated with various heat seal coatings which permit this method of unification of the dressing to be utilized. But it may be expedient to utilize a quick drying cement for uniting the film and the absorbent backing.

The cement chosen may or may not be pressure-sensitive but it should be water insoluble, non-toxic and flexible when dry. It should be capable of firmly bonding the specific film to the absorbent backing. Cements which are to be utilised for heat sterilizable dressings must be capable of withstanding such heats without deterioration and must have such non-flow characteristics both when at room temperature and when heated as not to reduce the porosity of the film below the minimum for dressings of this invention. Cements for bonding specific films are well known, examples of which with the specific films for which it has been found satisfactory are indicated in Table I. Also indicated in this table are the heat sealability and steam sterilizability of the listed films, a + sign indicating that the particular film has the particular property.

A special type of cement bonding may be preferred where the film utilized is solvent cast upon a moving surface to which the film is detachably adherent. At a point in the drying sequence, the film becomes quite firm with its surface still tacky. At this point the absorbent backing may be pressed against the tacky film to firmly unite the two. This same procedure may be used where the film having a melting point below the char point of the backing is hot melt spread or extruded upon a chilled surface with the absorbent backing applied at the proper time to the exposed molten surface of the film.

TABLE I

Film	Heat Seal-ability	Steam Steriliz-ability	Cement Formula
Cellophane		+	A or B
Cellophane (moisture proof)		+	A or B
Cellulose acetate	+	+	A or C
Ethyl cellulose	+		C
Cellulose acetate-butyrate	+	+	A
Polyvinyl chloride	+	+	D
Vinyl chloride-acetate copolymer plasticized with 20% dioctyl phthalate	+		D
Vinyl chloride-acrylonitrile copolymer	+		C
Vinyl chloride-vinylidine copolymer		+	A
Vinyl chloride-octylacrylate copolymer	+		C
Polyamide (alcohol soluble)		+	A
Polyvinyl butyral	+		B
Polyethylene	+		E
Vinyl acetate-crotonic acid plasticized with 20% dibutyl phthalate			C
Polyethylene terephthalate		+	A

Suitable cements as indicated in Table I are as follows:

Formula A

	Parts by Weight
Solution x — polyvinylethyl ether	13.4
Toluene	76.2
Solution y — water	10.3
70% aqueous solution wetting agent (Aerosol OT)	0.09
methyl cellulose	0.001

Add Solution x to Solution y with rapid stirring.

FORMULA B

	Parts by Weight
Milled pale crepe rubber	350
High molecular weight polyisobutylene	200
Glyceryl ester of hydrogenated rosin	350
Low molecular weight polyisobutylene	100
Rubber antioxidant	3
Heptane	2500

FORMULA C

	Parts by Weight
55% solids polyvinyl acetate emulsion	100
Dibutyl phthalate	30
Water	20

FORMULA D

	Parts by weight
Neoprene latex 601A	100
Geon polyblend latex 552 (a dispersion of a blend of polyvinyl chloride and butadiene-acrylonitrile copolymer)	100

FORMULA E

	Parts by weight
Milled Pale Crepe Rubber	76.5
Glyceryl ester of hydrogenated rosin	76.5
Zinc oxide	56.5
Titanium dioxide	14.5
Antioxidant	1.0
Heptane	540.0

Where a cement is utilized, it is preferable to spread it as thinly as possible, consistent with firm bonding. The optimum dried thickness is in the range of about .0002 to .0006 inch with the wet thickness varying inversely with solids content.

The absorbent backings for the dressings of this invention must be sufficiently absorbent to take up and retain a minimum weight of water equal to four times the weight of the backing as determined by the Absorbency Test for Purified Cotton set out on page 678 of the fourteenth revision of the Pharmacopoeia of the United States. We prefer a sheeted non-woven fibrous absorbent material such as those described in U.S. Patents 2,277,049, 2,528,793 and 2,625,733, particularly the cotton felts described in the latter two patents, or absorbent cellulose sheeted wadding made from wood pulp such as is sold under the trade name "Cellucotton". Such sheeted absorbent material is preferred because it affords a more uniform coverage over the fenestrations in the film and hence presents a fairly uniform absorbent capacity throughout the area of the dressing.

Other absorbent materials both fibrous and cellular, such as woven and knitted fabrics, cotton and absorbent sponge material may be utilized, but in general are less satisfactory than the preferred absorbent backings. Where gauze is utilized, it is preferable that it be as fine as 32 x 28 for the film contacting layer. Gauze as coarse as 20 x 12 is unsatisfactory for the film contacting layer but may be used for other layers.

In the layer of absorbent backing in immediate contact with the fenestrations in the films of the dressings of this invention, capillarity is very important. It has been found that materials which when submitted to the above mentioned Pharmacopoeia test require more than 30 seconds for complete submersion are not suitable for this film contacting layer. Fibrous absorbent cellulosic sheet backings, the density of which are less than .05 grams per cubic centimetre, are also generally unsuitable. It has been found that a 30 square centimetre piece of film pierced with holes to give an open area of .25% and having individual openings of the order of .125 mm diameter will not in sixty seconds pass any appreciable water into a vented vessel when subjected to a head of 1" of water. Yet the same film, when backed with a typical cotton felt backing and constituting a dressing of this invention, will pass through the film and the backing behind it approximately 125 grams of water under the same conditions.

The dressings of this invention may be sterilized if desired by the now well known gaseous methods, using various alkylene oxides such as ethylene oxide, either along or in dilution with certain fire-suppressive gases such as carbon dioxide. Such dressings may be packaged in double envelopes of plastic film or paper before sterilization so that hospital autoclaving will be unnecessary. Relatively cool gaseous sterilization methods permit the use of a great many films which either have too low melting points to withstand heat sterilization temperature or which are deteriorated by such heats. Examples of films which may be satisfactorily used when gaseous sterilization is employed are all of those appearing in Table I.

In general it is preferred to unite the film portion of the dressings of this invention in an imperforate condition to the absorbent backing and thereafter to make the openings in the film by one of several methods.

Perhaps the most practical method of making the otherwise finished dressing porous is to punch holes from the film side by means of rolls studded with piercing pins such as the pins on a cotton card. When a cushion roll is used on the absorbent backing side of the dressing, quite irregular holes, slits, minor tears and punctures are produced, but dressings so perforated are entirely satisfactory both from the functional and commercial appearance standpoint. It is preferred to punch holes with a plurality of different size pins and it has been found that using two rolls faced with No. 0 card cloth and two rolls of No. 2 card cloth, an optimum dressing may be produced.

Where the film material is thermoplastic and has a relatively low melting point, it is possible to impart the proper porosity to the otherwise finished dressing by means of localized heating whereby holes are melted such as by hot wires imbedded in non-conductive rolls to form a well distributed pattern of fenestrations in the film.

Proper porosity may also be imparted to the film after unification of the dressing by means of knife bearing rolls which slit the film intermittently or porosity may be obtained by means of high frequency electrical sparking.

Where the fenestration of the film is to be done prior to unification of the dressing it is quite feasible to perforate the film with a well defined pattern of perforations similar to the perforations in postage stamps. One must be particularly careful, however, especially with very small perforations, to avoid filling the perforations with laminating cement if that method of unification is used.

Proper porosity in films may also be obtained by a great many other methods such as froth casting, casting with removable suspended particles, air jet piercing and the like.

It has been found that the interrelated size, number and distribution f film holes or slits are extremely important for the proper functioning of the dressings of this invention. It is obvious that the holes must be of such

size and number as to pass at least a minimum of wound exudate. In general, it has been found that film holes of about .2 mm diameter spaced approximately .75 mm apart impart excellent functionality to dressings otherwise properly constructed. Generally it has been found that an open area of less than .25% of the film area is inadequate for proper drainage whether distributed over the film area as numerous small holes or as relatively fewer larger holes. Holes smaller than .01 sq.mm. appear to be inadequate.

At the other extreme are films having fenestrations of such size that the dressings made from them can no longer be considered truly non-adherent. It has been found that where there are numerous holes in which a 5 mm circle may be inscribed, sticking of the absorbent backing to the wound through the holes, is very probable. But where there is a maximum of 10% or less of holes in which circles greater than 2 mm and up to 5 mm may be inscribed and the remainder of the holes are of such size that only circles having diameters less than 2 mm may be inscribed, the dressing will substantially retain its non-adherent character.

The films listed in Table I in calipers ranging from .00025 inch to .002 inch were spread with the cements indicated opposite them in wet thickness up to .0015 inch. While the spread coatings were still tacky, absorbent backings of cotton felt, flannel, 44/40 mesh gauze and wood cellulose sheet wadding were spread over the cement coatings. After drying, the dressings were fenestrated by localized heating and by passing through card cloth covered rollers to give openings ranging from .0125 square mm to 12 square mm and open areas from .25% to 25%. Similar films indicated in Table I as heat sealable were run with the same backings through heat seal rollers which produced both overall surface sealing and fine mesh pattern heat sealing. These heat sealed dressings were fenestrated in the same manner as the cement unified dressings. Similar films were first fenestrated and then heat sealed to the absorbent backings. Samples of all of the dressings were sterilized by subjecting them to a mixture of 10% ethylene oxide and 90% carbon dioxide at a temperature of 80 for 6 hours. Additional samples indicated in Table I as being steam sterilizable were sterilized with saturated steam at 240°F. and 12 pounds pressure for 15 minutes. All of the dressings survived sterilization without appreciable damage. All proved satisfactory as non-adherent dressings.

Proof of the effectiveness of the dressings of this invention is to be found first in the results of carefully controlled animal experiments and, secondly in the findings of exhaustive clinical tests carried out on human surgical wounds.

The first animal experiments demonstrate the dramatic superiority, in the important quality of non-adherence, of the dressings of this invention compared to the two leading dressings in use today.

In these extensive experiments, similar paired wounds placed symmetrically on opposite sides of each animal were dressed on one side with the dressings of this invention and on the other side with plain gauze and petrolatum coated gauze respectively. The dressings were removed after 7 days with comparative adherence as summarized in Table II.

TABLE II

Dressing	% of Wounds in which Adherence Occurred after 7 days
Gauze	93%
Petrolatum Coated Gauze	26%
Dressings of the Invention	0%

It will be noted from the data that while none of the wounds dressed with the dressings of this invention showed adherence, sticking and disruption did occur in 93% of wounds dressed with plain gauze, and in 26% of wounds dressed with petrolatum gauze.

The results of a second series of studies carried out on experimentally produced wounds demonstrates the superior—and very surprising — healing obtained in wounds covered with the dressings of this invention.

Experimental wounds dressed with the dressings of this invention were microscopically compared, by a recognised authority on microscopic anatomy, after 14 days without prior dressing removal, with similar wounds symmetrically placed on the same animals dressed respectively with gauze and petrolatum

coated gauze. On fifteen rabbits tested, the dressings of this invention left wounds, all of which showed advanced healing over those dressed with plain gauze. Compared with wounds dressed with petrolatum coated gauze, healing was farther advanced in twelve wounds dressed with the dressings of this invention of fifteen pairs of similar wounds.

The results of clinical trial furnishes the final proof of the remarkable effectiveness of the dressings of this invention. Human wounds dressed with the dressings of this invention have good colour and present a clean appearance with a very thin slightly moist skin-like covering which quickly dries if the dressing is not replaced. At the time of writing this specification, nearly a thousand diverse cases of major and of minor surgery, the latter mostly severe traumatic wounds of the extremities were dressed with the dressings of this invention and graded on lack of adherence, adequate absorption and non-interference with wound healing. All but 8 of the performances in this clinical evaluation of the dressings of this invention were classified as "excellent" in all categories.

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